

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,177	12/17/2001	Clemence K. Dartey	MCP-300	3307

27777 7590 10/02/2003
AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 10/02/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,177

Applicant(s)

DARTEY ET AL.

Examiner

Susan Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Preliminary Amendment, and Request for Continued Examination filed 06/09/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/09/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "a method for reducing cholesterol... administering...composition of claim 5 " in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The preamble of the composition of claim 5 does

Art Unit: 1615

not include a cholesterol reducing agent. It is suggested to amend the claim to place it proper dependent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. US 5,952,393.

Sorkin teaches a composition for reducing serum cholesterol comprising mixture of long chain aliphatic alcohols, e.g., policosanol and phytosterol; and binders, coating agents, diluents, emulsifiers, suspension agents, or stabilizers (column 2, lines 7-67). The mixture of policosanol and phytosterol can be incorporated into a soft gelatin capsule, or coated with tablet coating agent, including cellulose (example 1). Example

Art Unit: 1615

1. also discloses the weight ratio of the long chain aliphatic alcohol to the excipients (binders, coating agents, diluents, emulsifiers, suspension agents, or stabilizers).

Sorkin does not teach the size of the gelatin capsule being less than about 200 μm . However, no criticality is seen in the particular particle size since Sorkin teaches the use of a similar composition for the same purpose, *e.g.*, aliphatic alcohol in composition useful for reducing serum cholesterol levels. The burden is shifted to the applicant to provide data showing that the gelatin capsule of Sorkin does not have the claimed particle size, and/or data to establish that the gelatin capsule of Sorkin would have a detrimental effect upon the desirability of encapsulating long chain alcohol for reducing serum cholesterol levels.

Claims 5-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. US 5,952,393, in view of Redding Jr. US 5,271,881.

Sorkin is relied upon for the reason stated above. Sorkin does not teach the size of the encapsulated long chain alcohol.

Redding teaches liquids core encapsulated by a capsule shell that comprises materials disclosed in table 3 (columns 6-7). Redding also teaches that alcohol can be used in liquids core (column 22, lines 65-68). The capsule having a size range of 5-15 μm (column 24, lines 57-60). Thus, it would have been obvious for one of ordinary skill in the art to modify Sorkin's cholesterol lowering composition using the capsule having a size range in view of the teaching of Redding to obtain the claimed invention, because the references teach the desires for coating alcohols in a capsule shell.

Claims 2-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mothes et al., in view of Cain et al. WO 98/47385.

Mothes teaches alcohol-containing granules coated with waxes, cellulose, gelatin, lactose, or starches (column 3, lines 45-51). The alcohol-containing granules can be incorporated in dry soups, sauces, desserts, and beverages (column 3, lines 53-59). Although Mothes is silent as to the teaching of the intended use being claimed, e.g., use of the encapsulated alcohol to reduce cholesterol in a vertebrae, the intended use is inherent since Mothes obtains the same result from the use of encapsulated alcohol as additives useful in dry soups, sauces, desserts, and beverages.

Mothes is relied upon for the reason stated above. Mothes is silent as to the teaching of long-chain alcohol.

Cain teaches long-chain alcohol incorporated in food products, which can be used to provide simultaneously cholesterol-lowering properties (page 2, lines 14-24). Thus, it would have been obvious for one of ordinary skill in the art to modify Mothes' alcohol-encapsulated granules using the long-chain alcohol in view of the teaching of Cain, because the references teach the desires for coating alcohol useful for food products. The expected result would be a healthier food product containing encapsulated long-chain alcohol useful to lowering cholesterol.

Respons to Arguments

Applicant's arguments filed 06/09/03 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention does not directed to, among other things, "excipients" which appears not to have a factual foundation to include "a food grade acceptable materials selected from the group consisting of coating polymers, waxes, and plasticizers" as currently required in the claims. Contrary to the applicant's argument, the excipients taught by Sorkin includes coating agents, which is a generic term, and therefore, permits the present of the claimed food grade acceptable materials, e.g., cellulose polymers and waxes.

Applicant argues that the examiner has not provide any evidence that the disclosure of fat emulsions could be combined with a disclosure of ethanol-containing granules. Applicant further alleges that Mothes does not disclose the claimed long chain alcohol since Mothes defined ethanol as being the alcohol (column 1, lines 6-9). Cain discloses long chain alcohols in a fat-continuous emulsion. The record contains no evidence of the equivalence between ethanol and the long chain alcohol affirmatively required in the claims. Contrary to the applicant's argument, the reason for combining Mothes and Cain is not upon the equivalence between ethanol and the long chain alcohol, but the subject matters disclosed in the references. It is noted that, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the

Art Unit: 1615

test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Mothes teaches that the alcohol-containing particles can be used in food products, e.g., dry soups, sauces, desserts, and beverages (column 3, lines 55-60). Accordingly, the term "desserts" taught by Mothes allows the present of margarines, cream, or food products that contains fat emulsion taught by Cain (page 1, 1st paragraph). Cain further teaches that it is known in the food art to incorporate long chain alcohols in beverages (page 1, 2nd paragraph). Thus, it is the position of the examiner that it would have been obvious for one of skill in the art to, by routine experimentation modifies the alcohol-containing particle in the beverages taught by Mothes using the long chain alcohol in beverages in view of the teaching of Cain to obtain the claimed invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Application/Control Number: 10/023,177

Page 8

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600